

Remarks

Claims 59-62, 64-65 and 88-94 are pending after entry of this amendment. Claim 63 is canceled herein without prejudice. Claims 59, 64, and 65 are amended herein to more distinctly claim the invention by deleting the term “native,” by deleting the phrases “from which a live chick can hatch” and “and can develop in the shell and hatch as a live chick,” and by adding the clause “wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed.” Claims 1-58, and 66-87 have previously been canceled. New claims 88-94 are added herein. Support for these amendments and new claims can be found in the original claim language and throughout the specification, as set forth below. It is believed that these amendments and new claims add no new matter. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application, entry of these amendments and new claims, and allowance of the claims to issue.

Applicants would like to thank Examiner Wilson for his courtesy and insights in the telephone interview with applicants on August 25, 2005. Pursuant to the telephone interview, applicants state that the claimed egg comprises an embryo that develops from the fertilization of an ovum inside the same shell that was deposited around the female pronucleus as it passed through the reproductive tract of a female bird before the egg was oviposited (laid), the act of fertilization occurring after the unfertilized egg is oviposited. This embryo, *i.e.*, a “native embryo,” is limited to an embryo that develops in and hatches from the same shell in which the female pronucleus used to make the embryo was formed.

35 U.S.C. § 112, first paragraph

Applicants acknowledge the withdrawal of the rejection of claims 59-62 and 64-65 under 35 U.S.C. § 112, first paragraph, based on alleged failure to comply with the written description requirement.

35 U.S.C. § 112, second paragraph

Claims 59, 64, and 65 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Office Action states that the phrase “native embryo” is indefinite because it is a relative term and that the claim does not state to what the embryo or

yolk is native. The Office Action acknowledges that a “native embryo” encompasses an “embryo that develops and hatches from the same shell in which the female pronucleus was formed.” The Office Action states that the sentence is not the only one describing the concept of “native embryos” and does not limit the definition to “embryos that develop and hatch in the same shell in which the female pronucleus was formed.” The Office Action goes on to state that the sentence describing “native” must also be considered, i.e., “native means growing, living or produced in its place of origin.” The Office Action alleges that the definition also includes an embryo that hatches from an embryo transplant, recipient shell because it grows and lives in the shell and is hatched from the shell. The Office Action also alleges that the transplant, recipient shell may also be considered the embryo’s “place of origin” because it is the place from which the bird hatches and is born from.

The Office Action states that the Examiner would consider withdrawal of the rejection if applicants concede that the phrase “native embryo” was intended to be limited to an “embryo that develops and hatches from the same shell in which the female pronucleus was formed” but has a broader meaning because of the way “native” is more broadly defined.

Claim 63 is canceled herein without prejudice, thereby rendering moot this rejection as it applies to this claim. Therefore, applicants respectfully request withdrawal of this rejection.

In order to expedite prosecution of the claimed invention and without conceding that the term “native” is indefinite, claims 59, 64, and 65 are amended herein by deleting the term “native” and by adding the phrase “wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed.” This phrase recites explicitly what applicants have urged is the definition of “native embryo” in the specification. Therefore, applicants claim what they consider to be their invention without the use of the term alleged to be indefinite. Support can be found in the specification on page 11, line 28 to page 12, line 1. Applicants believe that the amendment of claims 59, 64, and 65 overcomes this rejection and respectfully request the withdrawal of this rejection and allowance of amended claims 59, 64, and 65 and dependent claims 60-62.

35 U.S.C. § 102

A. Claims 59-65 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tanaka *et al.* (1994, *J. Reprod. Fert.*, Vol. 100, pg 447-449). The Office Action states that Tanaka *et al.* taught an oviposited chicken egg comprising a fertilized ovum (pg 447, col. 2, "Materials and Methods;" pg 448, Fig. 1) made by transferring a day-old fertilized ovum into the birth canal of the chicken. The Office Action also states that a shell formed around the fertilized ovum as it passed through the recipient hen's reproductive system; the egg was laid on the day following the transfer (pg 448, col. 1 line 4); and a chick hatched (pg 448, col. 2, first full paragraph, line 9). The Office Action goes on to state that the egg is oviposited as claimed because a shell forms around it and is passed through the birth canal. The Office Action states that the day-old fertilized ovum had less than 10,000 cells as claimed because a zygote is one cell. The Office Action goes on to state that the embryo is "native" as claimed because it grows, lives and hatches from the egg shell that forms around it in the female reproductive tract.

Further, the Office Action states that the shell that forms around the fertilized ovum (underline added) is the embryo's "place of origin," as used in the description of "native embryos" in the specification in the sentence bridging pages 11-12 because the shell is the place in which the embryo grows, lives and hatches. The Office Action states that a "native embryo" is not limited to an embryo that develops and hatches from the same shell in which the female pronucleus was formed as in the sentence bridging pages 11-12. The Office Action asserts that the definition of "native" on page 11, lines 27-29, is broader and encompasses any embryo growing, living or produced in its place of origin. The Office Action states that the embryo of Tanaka is growing, living and hatches from a shell that forms around the embryo (underline added) in the female reproductive tract; the shell that forms around the embryo (underline added) in the female reproductive tract is the embryo's "place of origin;" thus, Tanaka meets all the limitations of the claims.

Claim 63 is canceled herein without prejudice, thereby rendering moot this rejection as it applies to this claim. Therefore, applicants respectfully request withdrawal of this rejection.

Claims 59, 64, and 65 are amended herein by deleting the word "native" and adding the phrase "wherein the embryo develops and hatches from the same shell in which the female

pronucleus was formed.” Support can be found in the specification on page 11, line 28 to page 12, line 1.

Tanaka *et al.* teaches that an unfertilized ovum, removed from a donor hen, can be fertilized *in vitro* and then transferred after about 15 minutes into the infundibulum (upper part of a hen’s reproductive tract) of a recipient hen and then migrate down the tract over a day’s time to be laid in a shell that develops in the recipient hen around the fertilized ovum, and then incubated to produce a live chick. In contrast, the claimed egg comprises an embryo that develops in the same shell in which the female pronucleus, used to form the embryo, was formed.

The laid, fertilized egg in a shell in Tanaka *et al.* traveled the length of the oviduct in the recipient hen, and the approximate 24 hours that the egg traveled through the oviduct was the same time that a naturally fertilized egg in a hen would take to travel to the vagina to be oviposited (laid). Thus, as is well known in the art, the laid egg in Tanaka *et al.* had at least 30,000-60,000 cells. In contrast, the claimed invention comprises an embryo having fewer than 30,000 cells.

Further, the Office Action misreads the reference when it alleges that Tanaka *et al.* taught an egg that “had less than 10,000 cells as claimed because a zygote is one cell.” In fact, Tanaka *et al.* showed that a zygote made by *in vitro* fertilization could be transferred into the infundibulum of a recipient hen and then develop into an embryo as it traveled down the oviduct. The zygote was not in a laid egg in a calcified shell; rather, it was in the upper part of a hen’s oviduct without a surrounding shell. By the time the egg of Tanaka *et al.* was actually laid, it would contain more than 30,000 cells.

Tanaka *et al.* does not teach an oviposited avian egg, comprising a shell and an embryo, wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed, and wherein the embryo has fewer than 30,000 cells. Thus, claims 59-62 and 64-65 are not anticipated. Applicants, therefore, respectfully request withdrawal of this rejection and allowance of amended claims 59, 64, and 65 and dependent claims 60-62.

B. Claims 59-65 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Johnston (1998, *Poultry Science*, Vol. 77, page 142). Specifically, the Office Action states that Johnston taught an oviposited oocyte with a shell used for fertilization by injecting sperm onto the oocyte, which is equivalent to an oviposited chicken egg as claimed. The Office Action goes

on to state that the fertilized oocyte is equivalent to an embryo or zygote as claimed and is less than 10,000 cells as claimed because it is one cell that proliferates. The Office Action goes on to state that the fertilized oocyte is an “egg from which a live chick can hatch” because the fertilized oocyte proliferates. The Office Action goes on to state that without evidence to the contrary, the egg can hatch. The Office Action further states that the limitation “from which a live chick can hatch” does not distinguish the structure of the claimed egg from the structure of the egg described in Johnston.

The Office Action states that the embryo proliferating in a culture system described by Johnston is a “native” embryo because it is growing in its place of origin. The Office Action goes on to state that the embryo of Johnston is “native” because it grows in a culture medium which is “its place of origin” because fertilization took place in culture medium.

In the Advisory Action issued on December 22, 2005, the Examiner states “[a]pplicants argue the embryo taught by Johnston was not in a shell. Applicants’ argument is not persuasive. The embryo was in a shell and then removed. This is acknowledged by applicants on pg 7, last two sentences, of applicants’ response filed 11-17-05.” (underline added.) The Examiner further states that “[a]pplicants argue Johnston did not put the embryo back into the shell. Applicants’ argument is moot because the product claimed does not require putting an embryo back into a shell.” See Advisory Action, page 2, paragraphs 4 and 5.

Claim 63 is canceled herein without prejudice, thereby rendering moot this rejection as it applies to this claim. Therefore, applicants respectfully request withdrawal of this rejection.

Claims 59, 64, and 65 are amended herein by deleting the word “native” and by adding the phrase, “wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed.”

For a prior art reference to anticipate a claimed invention, each and every element of the claimed invention must be disclosed in that single reference. Further, the disclosure in that single reference must be enabling. If one element of the claimed invention is not disclosed in the prior art reference, there is no anticipation. It is settled law that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently.”

Verdegaal v. Union Oil, 814 F2d. 628, 2 USPQ2d 1051 (Fed. Cir. 1987).

Johnston does not disclose each and every element of the claimed invention. Specifically, Johnston does not disclose an oviposited avian egg, comprising a shell and an embryo, wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed, and wherein the embryo has fewer than 30,000 cells. In fact, Johnston does not even mention an embryo that develops and hatches from the same shell in which the female pronucleus was formed.

Further, the Examiner errs in the December 22, 2005 Advisory Action when he alleges that “[t]he embryo was in a shell and then removed. This is acknowledged by applicants on pg 7, last two sentences, of applicants’ response filed 11-17-05.” In fact, applicants stated in the response that “Johnston teaches the fertilization of an oocyte after it has been removed from the shell and separated from the thin and thick albumen enclosing it and adherent to it.” (underline added.) An oocyte is not an embryo. An oocyte is an unfertilized ovum containing a female pronucleus. An embryo is a developing organism resulting from the joining of a female pronucleus and a male pronucleus during the process of egg fertilization. See in the specification, page 8, lines 3-6. Further, an avian egg in a shell is an egg with a calcium carbonate shell that has been extruded from the vagina of the bird. See in the specification, page 7, lines 24-25. An unfertilized oocyte transferred into a weigh boat in Johnston is not an embryo in a shell. Nor is a fertilized oocyte in a weigh boat, as described in Johnston, an embryo in a shell. Thus, the culture system described in Johnston is not equivalent to the claimed egg. The culture system described in Johnston does not have the same structure as the claimed egg.

The Examiner’s incorrect allegation in the Advisory Action that the product claimed does not require putting an embryo back into a shell flows from the incorrect belief that the embryo in Johnston had initially been in a shell. In fact, the embryo in Johnston was never in a shell; only an unfertilized oocyte was in a shell. The embryo was created only after the unfertilized oocyte from which it was derived was first removed from the shell and then subsequently placed into a weigh boat where it was contacted with sperm. At this point, the oocyte was fertilized, and an embryo was created (came into being) *in vitro*, not in a shell. Johnston never created an embryo in a shell. Thus, the composition of matter in Johnston is not equivalent to the claimed egg.

Not only does Johnston not explicitly anticipate the claimed egg by setting forth each and every element of the claims, it does not anticipate the claimed invention inherently. Regarding inherency, M.P.E.P. § 2112 requires the Examiner to provide a rationale or evidence tending to show inherency. “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (Emphasis in original). Thus, for a claim to be rejected on the basis of inherency, the Examiner has the burden to show that a missing element of a claim is inherently present in the prior art and that this missing descriptive matter would be recognized by persons of skill in the art.

Applicants respectfully assert that the prior art does not inherently anticipate the claimed invention and that the Examiner has failed to meet his burden to show that a missing element of the claims, *i.e.*, “wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed,” is inherently present in the prior art and that this missing descriptive matter would be recognized by persons of skill in the art. The following describes the legal foundation for this conclusion.

In *In re Zierden*, 162 USPQ 102 (CCPA 1969), the question presented was whether claims to a method of removing alluvium from industrial waters, for example, water in cooling systems, were anticipated by a prior art reference [French patent] that disclosed a method for treating industrial waters to remove calcium carbonate scale that builds up in such cooling systems. The court held that because the prior art reference did not inherently teach that the industrial waters contained alluvium, the disclosed method did not necessarily result in the removal of alluvium. Thus, there was no anticipation of the claimed invention.

The dissenting judge stated that “if the industrial waters of the [prior art] French patent contain alluvium, even in a very slight amount, then the process of that patent inherently anticipates appellant’s process as claimed here.” (Emphasis added) There was no dispute between the majority and the dissent that if alluvium had been present in the waters, the prior art process would have inherently removed the alluvium. (Emphasis added). Further, it was not

disputed that it was very likely that alluvium was present in the waters. The majority opinion was based on the lack of certainty that alluvium was present in the waters.

In *Hansgirk v. Kemmer*, 102 F.2d 212, 40 USPQ 665 (CCPA 1939), the court emphasized that for a prior art reference to anticipate a claimed invention, the matter not explicitly described in the reference must necessarily be present in the reference. The court held that “[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”

The law on probabilistic inherency is set forth in *Continental Can v. Monsanto*, 948 F.2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991). The court held that “[t]o serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” (Emphasis added).

With regard to the Office Action’s rejection of claims 59-65, the Examiner has the burden to show that Johnston inherently describes, and a person of skill would recognize, an oviposited avian egg, comprising a shell and an embryo, wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed, and wherein the embryo has fewer than 30,000 cells.

Nothing is disclosed in Johnston to demonstrate that removing an oocyte from its shell and fertilizing it *in vitro* will result in an embryo that develops and hatches from the same shell in which the female pronucleus was formed. The Office Action is incorrect if it assumes that the methods disclosed in Johnston of fertilizing an oocyte *in vitro* necessarily result in an oviposited avian egg comprising a shell and an embryo, wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed, and wherein the embryo has fewer than 30,000 cells. In fact, the method of Johnston can never result in an embryo developing and hatching from the same shell in which the female pronucleus formed.

Moreover, the Office Action errs when it alleges that the egg in Johnston is “equivalent to an oviposited chicken egg as claimed.” See Office Action, page 6, last paragraph. The instant application teaches an oviposited avian egg comprising a shell and an embryo, wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed, and wherein the embryo has fewer than 30,000 cells. A person of skill would not recognize that an oocyte, removed from its shell and fertilized *in vitro* in a weigh boat as taught in Johnston, necessarily comprises a shell and an embryo, wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed, and wherein the embryo has fewer than 30,000 cells. Johnston does not teach an embryo in a shell; rather, it teaches an *in vitro* “culture system.” See Johnston abstract, line 3 from the bottom. Specifically, Johnston states, “[u]sing this culture system for 24 to 48 hours resulted in a few oocytes showing evidence of cellular proliferation.” (underline added.) Thus, the Office Action has failed to meet its burden of showing that the missing matter in this reference, *i.e.*, an embryo that develops and hatches from the same shell in which the female pronucleus was formed, is necessarily present. *Hansgirk*, 102 F.2d 212.

It is error for the Office Action to reject claims 59-65 because it is possible or even probable that some of the fertilized oocytes disclosed in Johnston may have possibly developed and hatched from the same shell in which the female pronucleus was formed. The Examiner has failed to show with certainty that the missing matter (an embryo that develops and hatches from the same shell in which the female pronucleus was formed) is present, and, thus, there can be no anticipation of these claims based on inherency. Therefore, applicants respectfully request that this rejection be withdrawn and that amended claims 59, 64, and 65 and dependent claims 60-62 be allowed.

C. Claims 59-65 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Naito (1990, *J. Exp. Zoo.*, Vol. 254, pages 322-326). Specifically, the Office Action states that Naito isolated a chicken embryo 2.5-2.75 hours after fertilization from the reproductive tract of a chicken and that the embryo was transferred into an eggshell with a hole drilled in it, incubated and hatched. The Office Action goes on to state that the embryo is a zygote because it is less than three hours old and that the egg is an “oviposited egg” because the egg has “a calcium

carbonate shell that has been extruded from the vagina of a bird,” as defined in the specification. The Office Action goes on to state that the embryo is “native” because it is in a shell from which it hatches, i.e., its “place of origin” and that the embryo is “native” to the recipient shell because the shell is the place in which the embryo grows, lives and hatches.

Claim 63 is canceled herein without prejudice, thereby rendering moot this rejection as it applies to this claim. Therefore, applicants respectfully request withdrawal of this rejection.

Claims 59, 64, and 65 are amended herein by deleting the word “native” and by adding the phrase, “wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed.” This amendment clearly distinguishes the claimed invention from Naito. Specifically, the embryo of Naito was taken from a donor bird’s reproductive tract prior to a shell being deposited around it. That shell, had it been deposited in the donor bird’s reproductive tract, would have been the shell that formed around the female pronucleus. However, the shell in Naito is a recipient shell from another bird in which the claimed female pronucleus did not form.

Therefore, applicants believe that this rejection is overcome and respectfully request withdrawal of this rejection and allowance of amended claims 59, 64, and 65 and dependent claims 60-62.

35 U.S.C. § 103

Claims 59-65 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Johnston (1998 *Poultry Science*, Vol. 77, page 142) in view of Goldberg (1992, *Ped. Research*, Vol. 32, pages 23-26). Specifically, the Office Action states that Johnston injected sperm onto an oviposited oocyte that had been removed from its shell. The Office Action alleges that the oviposited oocyte is equivalent to an oviposited chicken egg as claimed. The Office Action states that the fertilized oocyte is an “egg from which a live chick can hatch” because the fertilized oocyte proliferates. The Office Action goes on to state that the egg proliferating in a culture system described by Johnston is a “native” embryo as claimed because it is growing in its place of origin. The Office Action goes on to state that the embryo of Johnston is “native” because it grows in a culture medium, which is “its place of origin” because fertilization took

place in culture medium. The Office Action admits that Johnston did not teach injecting sperm onto the oocyte in the shell from which it came as described in the instant application.

The Office Action states that Goldberg taught injecting five solutions into eggs using a 1 mm window and that it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject sperm onto an oviposited chicken oocyte as taught by Johnston through a 1 mm window in the shell as taught by Goldberg. The Office Action goes on to state that one of ordinary skill in the art at the time of the invention would have been motivated to inject sperm onto the oocyte while the oocyte was still in the shell using a 1 mm window to decrease the amount of change to the oocyte's surroundings and to maintain the integrity of the egg. The Office Action states "the motivational statement is based on basic, non-scientific reasoning, i.e., injecting sperm through a hole in the shell would prevent the step of culturing the embryo in vitro and keep the embryo in its natural surroundings."

The Office Action states that "the fertilized oocyte described by Johnston could be transferred to a shell and hatch because Johnston taught the fertilized oocyte proliferates. Therefore, without evidence to the contrary, the egg described by Johnston can hatch." The Office Action goes on to state that the combined teachings of Johnston and Goldberg produce an egg having the same structure described in the instant application." See Office Action, page 10, paragraph 2.

The U.S. Patent and Trademark Office has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. See *In re Warner et al.*, 379 F.2d 1011, 154 U.S.P.Q. 173, 177 (C.C.P.A. 1967); *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988). "It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *Id.* Moreover, in rejecting a claim under 35 U.S.C. § 103, the Examiner must establish a *prima facie* case that: (i) the prior art suggests the claimed invention; and (ii) the prior art indicates that the invention would have a reasonable likelihood of success. See *In re Dow Chemical Company*, 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). In order for a reference to be effective prior art under 35 U.S.C. § 103, it must provide a motivation whereby one of ordinary skill in the art would be led to do that which the appellant has done. See *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1535, 218 USPQ 871,

876 (Fed. Cir. 1983). “One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). “When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned.” *In re Deuel*, 51 F.3d 1552, 1557, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995) (citing *Fine*, 837 F.2d at 1074).

Claim 63 is canceled herein without prejudice, thereby rendering moot this rejection as it applies to this claim. Therefore, applicants respectfully request withdrawal of this rejection.

Claims 59, 64, and 65 are amended herein by deleting the word “native” and by adding the phrase, “wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed.”

The Office Action alleges that the suggestion to combine prior art teachings can be found in the cited references. However, the present rejection does not find the required suggestion in either source. In fact, Johnston, as shown below, actually teaches away from the claimed invention. Moreover, Johnston teaches away from Goldberg. Therefore, a person of skill would have no reason to combine the references to make the claimed invention, and there would certainly be no expectation of successfully making the claimed invention. Nowhere has it been shown or argued that those of ordinary skill in the art had any general knowledge relevant to activating, for example by fertilization, an unfertilized oviposited (laid) avian egg.

The Office Action errs when it alleges that “the oviposited oocyte is equivalent to an oviposited chicken egg as claimed.” See Office Action, page 8, last paragraph. Johnston does not teach an oviposited avian egg, comprising a shell and an embryo, wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed, and wherein the embryo has fewer than 30,000 cells. Instead, Johnston created a complicated composition of matter comprising an ovum, removed from the shell in which the female pronucleus had developed, that was first treated by hydrolysis of the OPL with 0.01 N HCl before being contacted with sperm and cultured *in vitro* in medium of thin egg albumen and sterile PBS. Johnston does not disclose an embryo that develops and hatches from the shell in which the female pronucleus was formed.

Goldberg is a reference related to the study of cardiac teratogenicity of dichloroethylene in a chick model. Goldberg discloses something completely different from the claimed

invention. This reference does not teach, suggest or motivate a person of skill to activate an oviposited, unfertilized avian egg in a shell to produce an early developmental embryo with a reasonable expectation of success. In fact, the reference does not mention sperm or other means of activation at all. Goldberg was studying the effect of various chemicals on the development of embryos within an egg and did not even contemplate injecting sperm into an egg. Thus, Goldberg adds nothing to cure the deficiencies of Johnston.

A person of skill in the art would not be motivated to combine the teachings of Johnston and Goldberg to make the claimed invention with a reasonable expectation of success. Johnston teaches removing an unfertilized oocyte from the shell of an oviposited egg and placing the oocyte into a weigh boat. Johnston also teaches chemically disrupting the OPL with 0.01 N HCl to provide unimpeded access to sperm to penetrate the OPL to fertilize the oocyte. Goldberg teaches injecting chemicals into an egg through the shell and does not teach removing the contents of the oviposited egg from the shell. A person of skill in the art would not read Johnston and Goldberg together and have any motivation or a reasonable expectation of success that injecting sperm onto an oocyte could possibly produce an egg, comprising a shell and an embryo, wherein the embryo develops and hatches from the same shell in which the female pronucleus was formed, and wherein the embryo has fewer than 30,000 cells. Indeed, even after great efforts to modify the ovum, Johnston discloses only a few oocytes showing evidence of cellular proliferation, but fails to achieve an embryo that developed and hatched from the same shell in which the female pronucleus was formed. Thus, there would be no motivation to try fertilization in a shell without all the modifications to the ovum taught by Johnston.

Not only does Johnston teach away from Goldberg because it teaches removing the oocyte from the shell, but also Johnston teaches away from the claimed invention. Johnston teaches a totally different structure from the claimed invention. The *in vitro* oocyte of Johnston lacks a shell. In contrast, the claimed invention derives from the surprising discovery that the simpler process of injecting sperm through a shell can lead to fertilization of an ovum with successful development of an embryo that develops in and hatches from the same shell in which the female pronucleus was formed.

Neither Johnston nor Goldberg, alone or in combination, suggests producing the claimed invention. Only with the knowledge of the present invention and impermissible hindsight can a

rejection of claims 59-62 and 64-65 be made on the basis of obviousness. Thus, the Office Action fails to make a *prima facie* case for obviousness; therefore, these rejections are improper and should be withdrawn.

Applicants have created an innovative composition of matter, *i.e.*, a developmentally early avian embryo with characteristics that were desired but not accomplished or suggested by the art. In fact, applicants discovered that “injecting sperm through a hole in the shell would prevent the step of culturing the embryo *in vitro* and keep the embryo in its natural surroundings.” See Office Action, page 10, first paragraph. Indeed, the claimed novel composition is efficiently derived and results in an efficient breeding method that can revolutionize poultry breeding processes. Moreover, the large number of early embryos in their respective shells that can be produced by the methods associated with the claimed invention can also be utilized for high throughput transgenesis. In other words, the compositions of this invention can be created in large numbers and, thus, can be engineered in large numbers to produce a desired transgenic bird. Thus, the invention provides major advantages to the poultry industry that were desired but unobtainable from prior art methods. Applicants, therefore, respectfully request that these rejections be withdrawn and that amended claims 59, 64, and 65 and dependent claims 60-62 be allowed.

Double Patenting

Claim 64 is objected to under 37 C.F.R. § 1.75 as allegedly being a substantial duplicate of claim 63. Claim 63 is canceled herein without prejudice, thereby rendering moot this objection. Therefore, applicants respectfully request withdrawal of this objection and allowance of amended claim 64.

New claims

New claims 88-94 are added herein. Applicants believe that for the following reasons, these claims are patentable over the prior art.

The Office Action acknowledges that a “‘native embryo’ encompasses an ‘embryo that develops and hatches in the same shell in which the female pronucleus was formed.’” The Office Action also states that the sentence is not the only one describing the concept of “native

embryos” and does not limit the definition to “embryos that develop and hatches (sic) in the same shell in which the female pronucleus was formed.” The Office Action goes on to state that the sentence describing “native” must also be considered, which says, “native means growing, living or produced in its place of origin.” The Office Action alleges that a “native embryo” also includes “an embryo that hatches from a transplant, recipient shell because it grows and lives in the shell and is hatched from the shell. (underline added.) The Office Action also alleges that a transplant recipient shell may also be considered the embryo’s “place of origin” because it is the place from which the bird hatches and is born from.” (underline added). See Office Action, page 4, first full paragraph.

The Office Action misinterprets the definition of “native embryo” because it incorrectly interprets the term “place of origin.” The Office Action is wrong when it states that “place of origin” means the place from which the embryo hatches. Thus, the Office Action is wrong when it alleges that the “transplant recipient shell may also be considered the embryo’s ‘place of origin’ because it is the place from which the bird hatches and is born from.” (underline added). See Office Action, page 4, first full paragraph.

The word “native” as defined in the specification on page 11, lines 27-28 means “growing, living or produced in its place of origin.” Webster’s II College Dictionary defines “produce” to mean “manufacture.” See attached page 882 (shown as Exhibit A). “Manufacture” means “create.” See attached page 667 (shown as Exhibit B). Moreover, the definition of “origin” includes “a coming into being.” See attached page 773 (shown as Exhibit C). Thus, a native embryo is an embryo that is growing, living or created in its place of coming into being, i.e., in the place where the embryo is produced at the instant when the female pronucleus in an unfertilized oocyte is fertilized by contact with sperm that contains the male pronucleus. The claimed invention is a native embryo because it grows, lives and is produced in the place where it came into being at the moment of fertilization, i.e., in the same shell in which the female pronucleus was formed and in which fertilization takes place. Thus, the definition of “native embryo” in the specification is clear.

A native embryo does not include an embryo that is transplanted into a recipient hen’s oviduct where it is later surrounded by a shell because the embryo did not come into being in the recipient shell. Instead, the embryo came into being in a donor hen’s reproductive tract prior to

its being transferred into the recipient hen where subsequently a shell was laid down surrounding the embryo. (Tanaka).

Further, a native embryo does not include an embryo that was transferred into an eggshell with a hole drilled into it, incubated and hatched. The Examiner's allegation that Naito taught a native embryo because "it is in a shell from which it hatches, *i.e.*, 'its place of origin,'" is error. The place of origin of the embryo in Naito is the place where the embryo came into being, *i.e.*, the place where the unfertilized female pronucleus was fertilized and became an embryo. Thus, in Naito, the place of origin of the embryo is the reproductive tract of the donor chicken, not the recipient shell into which the embryo was transferred and from which it later hatched. It is not the place of hatching that determines the place of origin of an embryo, but rather the place where the embryo came into being, *i.e.*, the place where the oocyte containing the female pronucleus is fertilized.

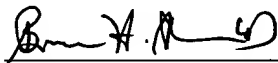
Pursuant to the above amendments and remarks, reconsideration and allowance of the pending claims and allowance of the new claims are believed to be warranted, and such action is respectfully requested. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issuance.

ATTORNEY DOCKET NO. 23101.0003U1
APPLICATION NO. 09/784,575

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of \$2,225.00 (small entity) (\$1,080.00 fee for a five (5) month extension of time, \$750.00 fee for a Petition for Revival of an Application for Patent Abandoned Unintentionally, and \$395.00 fee for a Request for Continued Examination under 37 C.F.R. § 114), a Request for Extension of Time, a Petition for Revival of an Application for Patent Abandoned Unintentionally, and a Request for Continued Examination are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

 7/11/06

Bruce H. Becker, M.D., J.D.

Registration No. 48,884

NEEDLE & ROSENBERG, P.C.
Customer Number 23859
(678) 420-9300
(678) 420-9301 (fax)